REMARKS

In response to the Office Action, claims 1 and 11 have been amended. Accordingly, claims 1-22 and 36-55 remain pending.

In the Office Action, claims 1, 2, 4 and 9 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,776,785 ("the Yencho et al. reference"), and claims 1, 2, 4, 5, 7-16, 18, 21, 22, 36-41, 43-47, 49, and 52-55 were rejected either under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,371,983 ("the Lane reference"). Finally, claim 6 is rejected under 35 U.S.C. § 103(a) as unpatentable over the Lane reference in view of U.S. Patent No. 6,241,765 ("the Griffin et al. reference"), claim 17 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Lane reference in view of U.S. Patent No. 6.409,759 ("the Peredo reference"), and claims 19, 20, 42, 48, 50, and 51 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Lane reference in view of U.S. Patent No. 6,893,459 ("the Macoviak reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the Yencho reference, a one piece anastomosis device is disclosed for connecting a graft vessel to a target vessel. (Col. 1, line 66 to col. 2, line 1). In one embodiment, the anastomosis device 80 includes a device body 84 formed of a plurality of substantially parallel spring elements interconnecting end members 88. (Col. 6, lines 3-5). Thus, the end members are not separate components of a multiple-component device, but are elements of a single device.

Turning to the present claims, claim 1 recites a multiple-component heart valve assembly that includes a base member generally defining a plane and comprising a multi-lobular annular shape within the plane; an annular body separate from the base member and comprising a multi-lobular shape complementary to the multi-lobular shape of the base member; and cooperating connectors on the base member and the annular body for connecting the annular body to the base member after the base member has been introduced into a tissue annulus.

First, the Yencho reference fails to disclose, teach, or suggest anything about ***heart valve assemblies*** nor ***multiple-component*** heart valve assemblies, as claimed but merely discloses one piece anastomosis devices. Further, even if the end members of the Yencho reference qualified as a base member and an annular body, the end members are never ***separate from*** one another, but are formed as a single piece. Finally, the Yencho reference does not teach or suggest cooperating connections on the base member and annular body ***for connecting*** the annular body to the base member ***after the base member has been introduced into a tissue annulus.*** Instead, the Yencho reference merely discloses spring members that permanently interconnect the end members, and are incapable of not being connected to one another. Accordingly, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Yencho reference.

Turning to the Lane reference, a one piece bioprosthetic heart valve 11 is disclosed that primarily includes three components, namely: (1) leaflet tissue, (2) a plurality of laminated elastic inner frames, and (3) a supporting outer frame having an attached sewing ring. (Col. 3, lines 19-22). The inner frame 13 includes three separate inner frame assemblies 18 that support valve leaflets 15 in stand-alone fashion. (Col. 3, line 59 to col. 4, line 7). Each inner frame 18

includes laminates of crescent-shaped struts carrying an individual leaflet 15 and attached to the outer frame by anchoring pins 23. (Col. 4, lines 22-45). The outer frame 25 is covered with cloth, a section of which is gathered to construct the sewing ring 17. (Col. 5, lines 17-20).

Turning to claim 1, the Lane reference fails to disclose, teach, or suggest anything about ***multiple-component*** heart valve assemblies generally, nor an annular body ***separate from*** a base member, in particular, as claimed. In fact, the Lane reference does not teach or suggest an annular body, but instead discloses a plurality of crescent-shaped laminates that are individually attached to an outer frame "in stand-alone fashion." Thus, these individual laminates cannot constitute an annular body, as claimed.

In addition, the Lane reference does not teach or suggest cooperating connectors on the base member and the annular body for connecting an annular body to a base member ***after the base member has been introduced into a tissue annulus***. Even if the individual laminates of the Lane reference somehow constituted an annular body, the anchoring pins do not connect the annular body to a base member ***after*** the base member has been introduced into a tissue annulus. In contrast, the anchoring pins are used during manufacturing to attach the individual laminates to the outer frame, and the entire bioprosthetic heart valve is then introduced into a tissue annulus together as one piece. Accordingly, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Lane reference.

For similar reasons, claim 11 is also not anticipated by the Lane reference. Claim 11 also recites a ***multiple-component*** heart valve assembly and an annular body ***separate from*** a base member, which are neither taught nor suggested by the Lane reference, as explained above. In

addition, claim 11 recites guides on at least one of the base member and the annular body for aligning the multi-lobular shapes with one another about the longitudinal axis before the annular body is attached to the base member. No such guides are taught or suggested in the Lane reference. Holes in the Lane laminates cannot constitute the claimed guides, because, unlike the claimed guides, which ***align the multi-lobular shapes*** of the annular body and the base member, the holes in the Lane laminates merely receive anchoring pins to secure individual laminates to the outer frame. There is no multi-lobular shape to align in the Lane device until the individual laminates are all attached to the outer frame, and thus the holes do not align an annular body with a base member.

Finally, the holes that receive the anchoring pins are not oblong, but are circular corresponding to the diameter of the anchoring pins, as clearly shown in FIG. 5 (where both the pins and the holes have the same circular shape). The pins are not intended to slide freely within the holes in the laminates because such movement would allow the leaflets to move freely, thereby preventing the valve from opening and closing in a predictable manner during use within a patient's heart. Instead, the anchoring pins secure the midpoints of the laminates from movement, while allowing ends of the laminates to move during opening and closing of the valve.

The other holes 26 in the laminates, some of which are shown as oblong, are not for receiving anchoring pins but are intended to provide desired flexural properties to ends of the laminates or to receive sutures, as explained at col.5, lines 34-48. The oblong shape of these holes is merely exemplary, and "the requirement and the geometry of apertures 26 that are

provided in the laminated structure are determined through finite element stress analysis," i.e., to provide the desired flexibility. Id. Accordingly, claim 11 and its dependent claims are also neither anticipated by nor otherwise obvious over the Lane reference.

Turning to claim 36, a heart valve assembly is recited that includes a base member comprising a generally annular shaped body and a flexible cuff extending around a periphery of the annular shaped body; a valve member comprising a multi-lobular shape; and one or more elongate guide members extending from the base member and receivable through the valve member such that the valve member is slidable along the one or more guide members to align the valve member with the base member as the valve member is directed towards the base member.

The Lane reference fails to disclose, teach, or suggest one or more elongate guide members extending from the base member, as claimed. Such guide members are shown, for example, in FIGS. 31-34 of the present application, and allow the valve member to ***slide along the guide members***, e.g., into a tissue annulus towards the base member, which has already been introduced into the tissue annulus. As explained above, the anchoring pins of the Lane reference do not allow a valve member to slide therealong, but attach and secure the midpoints of the individual laminates to the outer frame. Further, the anchoring pins of the Lane reference do not align a valve member with a base member as the valve member is directed towards the base member. Again, they merely attach individual laminates to an outer frame during assembly.

It is unclear whether the tethers disclosed in the Lane reference are being interpreted as constituting guide members, but since the tethers merely loosely connect the tips of adjacent

laminates, they do not extend from a base member, as claimed, and therefore cannot meet the claimed guide members.

The deficiencies of the Lane references are further reinforced, for example, by claim 37, which recites that the valve member includes a frame having a multi-lobular shape and a plurality of leaflets. The only frame of the Lane reference having a multi-lobular shape is the outer frame, which has already been identified as the base member. For these reasons, claim 36 and its dependent claims are neither anticipated by nor otherwise obvious over the Lane reference.

Turning to claim 52, for similar reasons to those given above, the Lane reference does not disclose, teach, or suggest a plurality guide members spaced apart around a periphery of the base member such that the valve member is slidable along the guide members to align the valve member with the base member as the valve member is directed towards the base member. Finally, if the anchoring pins of the Lane reference are the recited guide members, the Lane reference fails to disclose, teach, or suggest cooperating connectors for securing the valve member adjacent the base member, since the anchoring pins are the connectors disclosed in the Lane reference. Accordingly, claim 52 and its dependent claims are also neither anticipated by nor otherwise obvious over the Lane reference.

In addition, the Lane reference does not teach or suggest guide members being detachable from a base member, as recited in claim 55. In fact, if the anchoring pins constitute the claimed guide members, they are necessarily not detachable, because they secure the laminates and leaflets to the outer frame, which is necessary for the operation of the valve in a patient.

Finally, turning to the other cited references, none of these references disclose, teach, or suggest the features in the independent claims that are wholly absent from the Lane reference. For example, none of the other cited references discloses, teaches, or suggests an annular body separate from a base member, both having multi-lobular shapes, nor elongate guide members extending from a base member that allow a valve member to slide along the guide members. Accordingly, the present claims are not obvious even if the other cited references could be properly combined with the Lane reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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